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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

July 17, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 28

Daniel D. Siemers
President
Siemers Holsteins, Inc.
14421 Mineral Springs Road
Newton, Wisconsin 53063

Dear Mr. Siemers:

On May 7 and 13, 2003, an investigator from the Food and Drug Administration (FDA) conducted an inspection at your dairy farm located in Newton, Wisconsin. That inspection revealed that you caused an animal drug to be unsafe under Section 512(a) of the Federal Food, Drug and Cosmetic Act (the Act) and adulterated within the meaning of Section 501(a)(5) of the Act because the drug was used in a manner that does not conform with its approved use or the regulations for Extralabel Drug Use in Animals [Title 21, Code of Federal Regulations, Part 530 (21 CFR Part 530)].

On or about March 13, 2003, you offered a dairy cow (your ear tag number 2851) for slaughter as human food to [redacted] U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow (backtag 35 HWO 158) identified the presence of flunixin at 3.70 ppm in the liver. A tolerance of 0.125 ppm has been established for residues in cattle liver (21 CFR 556.286).

Flunixin is not approved for use in lactating or dry dairy cows per 21 CFR 522.970. However, the extralabel use of an approved veterinary or human drug is permitted if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 CFR Part 530. Our investigation found that your extralabel use of flunixin failed to comply with these requirements. The deviations include:

- You administered flunixin to cow number 2851 in a manner contrary to label directions without the supervision of a licensed veterinarian. Under 21 CFR 530.11(a), extralabel use by a layperson is not permitted except under the supervision of a licensed veterinarian.

- Your extralabel use of flunixin resulted in an illegal drug residue. 21 CFR 530.11(d) prohibits any extralabel use that results in a residue above an established tolerance level.

Because your extralabel use of flunixin was not in compliance with 21 CFR Part 530, the drug is unsafe under Section 512(a) of the Act. As a result, your use of this drug caused it to be adulterated within the meaning of Section 501(a)(5) of the Act.

It is not necessary for you to personally ship an adulterated drug in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of a drug that had been sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

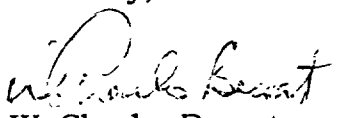
The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the foods you distribute are in compliance with the law. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

We have enclosed a copy of 21 CFR Part 530 for your reference. We strongly suggest that you review 21 CFR Part 530 and become familiar with all of its requirements so that you can prevent future violations of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,



W. Charles Becoat
Director
Minneapolis District